



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-18-18ARO; Docket No. ATSDR-2018-0007]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Prenatal Assessment of Environmental Risk (PAER)". This web-based data collection will provide information on behavioral risks for environmental exposures for patients seeking preconception and prenatal care, and for their reproductive health care clinicians (RHCCs).

DATES: ATSDR must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2018-0007 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffery M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Prenatal Assessment of Environmental Risk (PAER) - NEW - Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

Many environmental chemicals absorbed or ingested by pregnant women can cross the placenta to the fetus. The scientific evidence over the last 10 to 15 years has shown that exposure to toxic environmental agents before conception and during pregnancy can have significant and long-lasting adverse effects on the reproductive health of mothers, and on the long-term health of mothers and babies. Reducing exposure to toxic environmental agents is a critical area of intervention for reproductive health care professionals in the United States and worldwide. In 2013, the American College of Obstetricians and

Gynecologists (ACOG) and other obstetrician-gynecologist professional societies called for timely action to identify and reduce exposure to toxic environmental agents while addressing the consequences of such exposure (ACOG, 2013; FIGO, 2105).

In support of this call to action, the Agency for Toxic Substances and Disease Registry (ATSDR) is requesting a three-year Paperwork Reduction Act (PRA) clearance for a new information collection request (ICR) entitled "Prenatal Assessment of Environmental Risk (PAER)".

The long-term goal is for the PAER web-based information collection system to be widely adopted by obstetricians, gynecologists, and other reproductive health care professionals. Through PAER, practicing clinicians will have readily accessible and reliable information, and educational resources to counsel mothers-to-be on their potential environmental exposures and associated risks. This will facilitate reduction in harm to mothers-to-be and their babies. PAER environmental exposure assessment results will be suitable for incorporation into patients' electronic health records and maintenance within health care provider organizations.

Data collected will also establish an ongoing public health surveillance system that will provide an improved understanding of behaviors in daily life that put women of reproductive age

and their babies at higher risk of exposure to environmental hazards. ATSDR will maintain only anonymous patient PAER survey responses and registration variables, including the PAER unique survey ID number, age, and zip code. Age and zip code will serve as the two variables for data analysis. Reported risk-based aggregate data will be at the zip code or higher geographic level, excluding zip code tabulation areas (ZTCAs) with 20,000 or fewer persons.

ATSDR plans to analyze the exposure risk data by geographic regions and over time. This data analysis will allow clinician and patient education on the most prevalent region-specific environmental exposures. ATSDR and partner organizations can use this information to shape educational initiatives and counseling guidance on ways women can lower environmental exposure risk.

The PAER survey is web-based, and includes 17 multiple-choice questions and one open-ended question. These questions are divided into five topic areas: lifestyle; home; food and water; cans, bottles, and containers; and getting ready for the baby. The PAER survey focuses on 11 common types of environmental exposures: air pollution, benzene, bisphenol A (BPA), flame retardants, lead, mercury, polychlorinated biphenyls (PCBs), pesticides, phthalates, smoking, and volatile organic compounds (VOCs).

There are two types of respondents who will participate in the PAER data collection, reproductive health care clinicians (RHCCs), and women of reproductive age who are seeking preconception or prenatal care. RHCCs will include obstetricians/gynecologists, family medicine physicians, nurse practitioners and physician assistants, and nurse midwives who are involved in the care of these women.

RHCCs (the first type of respondent) who choose to participate in the PAER process will be required to register with ATSDR, and gain approval to participate and establish credentials through CDC's Secure Access Management Services (SAMS). ATSDR will provide online training resources to instruct RHCCs how to register themselves and their clinic for PAER, to recruit patients, to utilize environmental histories and PAER resources for patient counseling, and to link PAER results to their patient health records. Online registration and training module components are estimated to take 30 minutes per RHCC.

Each RHCC who participates in PAER will also invite their patients to complete the environmental exposure survey by email or text, link their patients' survey response data with the invitations sent and health records, and provide counseling to individual patients to aid in modifying behavior to lower

environmental exposure risks. These components are estimated to take RHCCs 30 minutes per patient.

Of note, ATSDR will not receive any information from the patients' electronic health records. RHCCs will invite their patients to participate outside of the PAER application, and will be responsible for protecting the patient information provided to them within PAER in accordance with the 1996 Health Insurance Portability and Accountability (HIPAA) guidelines.

Based on ACOG estimates, the number of practicing RHCCs in the U.S. is approximately 35,586. On average over the next three years, ATSDR estimates that up to 15 percent (n=5,338) of these clinicians will participate in the PAER process each year through online registration and training. For purposes of estimation, ATSDR assumes the RHCCs represent the full effort of clinic staff. The annualized frequency of response (12 per RHCC) is based on ATSDR assumptions about the number of patients who will take part in the PAER survey as described below.

Women who receive preconception or prenatal care (the second type of respondents) may respond to the PAER environmental exposure history by accessing the online PAER survey through the application internet home page or through their RHCC's email/text invitation. ATSDR assumes that 5 percent of these women will participate in PAER over the next three

years (or 1.67 percent per year). Using the 3,978,497 births reported in the 2015 U.S. Vital Statistics to represent the number women who receive preconception or prenatal care, 1.67 percent equals to 66,441 women who will take part in the PAER survey each year. Thus, each RHCCH is assumed to interact with 12 such patients per year ($66,441/5,338 = 12$). The time for women to respond to the survey is estimated at 10 minutes per patient.

Participation in the PAER process and survey is voluntary. There is no cost to respondents other than their time. The total annualized time burden requested is 45,772 hours. A summary of the estimated annualized burden hours is shown in the table that follows.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Reproductive Health Care Clinicians (RHCCs)	PAER Online Registration for RHCCs	5,338	1	15/60	1,335
	PAER Training Materials for RHCCs	5,338	1	15/60	1,335

	PAER Email/T ext Invitat ion, Data Linkage , and Counsel ing	5,338	12	30/60	32,028
Women who Receive Preconcept ion or Prenatal Care	Access and Respond to PAER Survey	66,441	1	10/60	11,074
Total					45,772

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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